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TITLE: Legacy Clinical Data from the Mission Connect Mild TBI Translational Research Consortium

PRINCIPAL INVESTIGATOR: Claudia Robertson, MD

CONTRACTING ORGANIZATION: Baylor College of Medicine
Houston, TX 77024

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6. AUTHOR(S)

Claudia Robertson, MD

E-Mail:claudiar@bcm.edu

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Baylor College of Medicine
One Baylor Plaza
Houston, Texas 77030-3411

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The long-term goal of the Mission Connect Mild Traumatic Brain Injury (mTBI) Translational Research Consortium was to improve the diagnosis and treatment of mTBI. We enrolled a total of 88 mTBI patients and 73 orthopedic injury (OI) control patients into observational studies, and a total of 50 mTBI patients in a clinical trial. The patients were enrolled within 24 hours of their injury, and followed for up to 6 months for the observational studies, and for 3 months for the clinical trial. The data that has been collected as a part of our study is potentially valuable to other investigators because it includes very early assessment of neurological status (within 24 hours of injury) and long-term (6 months) follow-up. The data includes neuropsychological assessment, advanced magnetic resonance imaging, electroencephalogram, and magnetoencephalogram in addition to detailed clinical information about the patient and the injury severity. The goal of the current funding was to submit the clinical data to FITBIR so that it could be made available to other investigators not involved in the project in order to accelerate research.

15. SUBJECT TERMS
Mild traumatic brain injury, MRI imaging, electroencephalogram, magnetoencephalogram, neuropsychological assessment

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Table of Contents

Page

1. INTRODUCTION:

The long-term goal of the Mission Connect Mild Traumatic Brain Injury (mTBI) Translational Research Consortium was to improve the diagnosis and treatment of mTBI. The data set resulting from the project was designed and structured to answer the explicit research questions posed in the specific aims of three observational studies and a clinical trial. To accomplish these four specific aims, we planned a single cooperative project, called the Integrated Clinical Protocol. We enrolled a total of 88 mTBI patients and 73 orthopedic injury (OI) control patients into the observational studies, and a total of 50 mTBI patients in the clinical trial. The patients were enrolled within 24 hours of their injury, and followed for up to 6 months for the observational studies, and for 3 months for the clinical trial. The data that has been collected as a part of our study is potentially valuable to other investigators because it includes very early assessment of neurological status (within 24 hours of injury) and long-term (6 months) follow-up. The data includes neuropsychological assessment, advanced magnetic resonance imaging (MRI), electroencephalogram (EEG), and magnetoencephalogram (MEG) in addition to detailed clinical information about the patient and the injury severity. The goal of the current funding was to submit the clinical data to FITBIR so that it could be made available to other investigators not involved in the project in order to accelerate research.

2. KEYWORDS:

Mild traumatic brain injury, MRI imaging, electroencephalogram, magnetoencephalogram, neuropsychological assessment

3. ACCOMPLISHMENTS:

- **What were the major goals of the project?**

Specific aim 1. To format clinical/research data from patients enrolled in our mild TBI studies so that the data can be submitted to FITBIR for sharing with other investigators.

Major Task 1: Project start up. Milestone achieved month 2
Major Task 2: Document, data, and technical preparation. Milestone achieved month 8
Major Task 3: FITBIR form building, data validation, and submission. In progress – completed for most forms
Major Task 4: Data query and final review. In progress – completed for many forms
Major Task 5: Project Close-out.

- **What was accomplished under these goals?**

The data that has been uploaded to FITBIR is detailed in the table below.

DATA UPLOADED TO FITBIR

Totals to date in Project	35,351	1,413	7
	ROWS	EXISTING	NEW UDE
1st Quarter Sep-Dec 2016	**4,511**	**154**	**7**
GCS	177	12	
GCS Appendix	177	8	3
Comp & Litigation	437	13	2
DAST10	452	17	
DAST10 Appendix	452	12	2
EHI	177	9	
EHI Appendix	177	12	-
AUDIT	452	17	
AUDIT Appendix	452	12	-
CDRISC	779	31	
CDRISC Appendix	779	11	-
2nd Quarter Jan-Mar 2017	**8,040**	**239**	**-**
CES-D	779	30	
CES-D Appendix	779	15	-
GOAT	104	30	-
GOAT Appendix	104	20	-
EEG	582	89	
EEG Data .zip source			
std_EEG_AmplitudeFreq_Summary	582		
std_EEG_Coherence_Summary	582		
std_EEG_DescriptiveComments	582		
std_EEG_Occipital_Summary	582		
std_EEG_Subjects	582		
std_EEG_Coherence_Raw	582		
RMEAD	1,100	35	
RMEAD Appendix	1,100	20	
3rd Quarter Apr-June 2017	**1,949**	**191**	**-**
PCLC	275	26	
PCL-C Appendix	275	20	
GOAT Appendix			
MACE	468	31	
MACE Appendix	156	15	
Consent	177	21	
Consent Appendix	177	18	
Protocol Deviations	216	15	
Adverse Events	180	27	
Adverse Events Appendix	25	18	
4TH Quarter July-Sept 2017	**20,851**	**829**	**-**
VSVT	604	60	
VSVT Appendix	604	16	
LAB	2,345	44	
LAB Appendix	337	14	
DKEFS VFT	3,577	78	
DKEFS VFT Appendix	511	16	

MEG	91	78
VitalSigns_FITBIR	177	13
ANAM.Zip Source		
std_ANAM_Results	6,566	
std_ANAM	707	
BVMT		
BVMT Appendix		
MedHx_FITBIR	338	218
MedHx_FITBIR Appendix	177	15
SDMT_FITBIR	1,208	28
SDMT_FITBIR Appendix	604	16
BVMT	604	49
BVMT Appendix	604	16
MRI (Imaging Read)	365	150
MRI Appendix	285	18
MRI Image files	1,147	

The items remaining to be uploaded include the Delis-Kaplan Executive Function System (DKEFS) test, Automated Neuropsychological Assessment Metrics (ANAM) test, the Patient Treatment History Form, the Injury History Form, and the Clinician Administered PTSD Scale (CAPS), the Short Form Survey (SF-12), Acute Stress Disorder (ASD)/Post-Traumatic Stress Disorder (PTSD), Acute Concussion Evaluation (ACE) test, and Return to School/Work.

- **What opportunities for training and professional development has the project provided?**

Nothing to Report

- **How were the results disseminated to communities of interest?**

Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**

Sierra Fourwinds, who is the data manager for the project, had to take a sudden medical leave at the end of this funding year and we were not able to finish the project as planned. We have been granted a 6 month no cost extension, and will be able to finish uploading and verifying the remaining data within this time frame.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

  Nothing to report

- **What was the impact on other disciplines?**

  Nothing to report

- **What was the impact on technology transfer?**

  Nothing to Report

- **What was the impact on society beyond science and technology?**

  Nothing to Report

5. **CHANGES/PROBLEMS:**

Nothing to Report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

  The only delay that we encountered which prevented completion of the project this year was the medical leave required by our data manager. She is back at work now and will be able to complete the project within the 6 month no cost extension.

6. **PRODUCTS:**

Nothing to Report

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name: Claudia Robertson, MD
Project Role: PI
Researcher Identifier ORCID ID/0000-0002-8509-678X
Nearest person month worked: 1
Contribution to Project: supervised the entire project, facilitated Sierra Fourwind's work to correctly map the clinical data to the FITBIR elements

Name: Shiny Abraham
Project Role: Research Coordinator
Researcher Identifier
Nearest person month worked: 2
Contribution to Project: Worked with Dr. Robertson and Sierra Fourwinds to coordinate the day-to-day activities of the projects. She has helped Sierra Fourwinds with editing/creating study documents, verifying elements to be submitted, defining the recoding or data transformation that are needed, creation of the FITBIR data forms, and reviewing data that is submitted

Name: Marianne MacLeod
Project Role: Research Assistant
Researcher Identifier
Nearest person month worked: 2
Contribution to Project: Worked with Dr. Robertson and Sierra Fourwinds to coordinate the day-to-day activities of the projects. She has helped Sierra Fourwinds with editing/creating study documents, verifying elements to be submitted, defining the recoding or data transformation that are needed, creation of the FITBIR data forms, and reviewing data that is submitted

Name: Brian Biekman
Project Role: Research coordinator
Researcher Identifier
Nearest person month worked: 1
Contribution to Project: Worked with Dr. Wilde to submit the MRI images

Name: Sierra Fourwinds
Project Role: PI of Silverwind subcontract
Researcher Identifier
Nearest person month worked: 2
Contribution to Project: Responsible for creating the data elements and forms, transforming our data to fit the FITBIR standards, and submitting the data

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

  For Dr. Robertson, NIH grant #2R44NS076167-02A1 ended 8/31/2016 and the following two grants have started:

  Development and Validation of Spreading Depolarization Monitoring for TBI Management (CoPI – 0.30 CM effort), Department of Defense, 7/1/17-6/30/20, $37,600.

  Rapid Portable Non-invasive Intracranial Pressure Assessment and Screening System (PI – 0.70 CM effort), Vivonics, Inc., 8/1/16-7/31/18, $69,420.

- **What other organizations were involved as partners?**

  Nothing to Report

8. **SPECIAL REPORTING REQUIREMENTS**

   N/A

9. **APPENDICES:**

   None